

Remarks

The October 4, 2005 Requirement for Restriction issued in the above-identified patent application has been carefully reviewed. The Examiner contends that the originally filed claims are directed to five (5) distinct inventions. These are as follows:

Group I: Claims 1-36 and 49-57 drawn to a drug screening method and proteins;
Group II: Claims 40-41 drawn to methods of treatment;
Group III: Claims 42-45 drawn to a diagnostic method;
Group IV: Claim 58 drawn to a method of preventing obesity; and
Group V: Claims 59 and 48 drawn to a method of determining a treatment modality.

It is the Examiner's position that the inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1, because, under PCT Rule 13.2, they lack the same or corresponding special technical feature. In the event, Applicant chooses to elect the Group I invention, the Examiner requires a further election of each of the following species- A: specific drug used in reduction of body weight; B: a single medical condition, C: a single genetic mutation and D: a single species of animal; and E: a single protein from those listed in the application each of these comprises a patentably distinct invention. Applicants must also indicate which claims read on the elected species.

Applicants strenuously traverse this election of species requirement. Indeed, the methods of the invention are suitable to screen ANY agent useful for treating an eating disorder, thus the requirement that Applicants elect a single agent (election A), e.g., leptin, is inappropriate. Likewise, the type of mutation present in the test animal to be studied

(election C) does not comprise the heart of the invention. Such animals merely provide suitable subjects for practicing the methods of the invention. It is Applicants position that any protein which exhibits differential expression in the subjects set forth in the claims is encompassed by invention. Thus, the election of a single protein from claim 31 is onerous and unwarranted. It is respectfully requested that the Examiner re-consider this requirement for the foregoing species elections.

Applicants respectfully assert that the restriction requirement set forth above is improper for failure to comply with the relevant provisions of the Manual of Patent Examining Procedure (M.P.E.P.) pertaining to unity of invention determinations.

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application under the Patent Cooperation Treaty.

As stated in § 1893.03(d) of the M.P.E.P.:

Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. § 371...

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art....

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as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1, because, under PCT Rule 13.2, they lack the same or corresponding special technical feature.

The requirements of the PCT are, of course, supposed to take precedence over normal national practice for the national phase of a PCT application. In particular, it is not permissible under the PCT for national offices to require compliance with the requirements relating to the form or contents of the application different from or additional to those which are provided for in the PCT (Art 27 PCT). In this specific instance, the PCT Handbook says at section 33.35, paragraph 2 "a designated office ought not to raise an objection as to a lack of unity when the International Searching and/or Preliminary Examining Authority has found that the claims comply with the requirement for unity of invention". Indeed, the PCT Contracting States have agreed to this principle, according to the PCT Handbook at Section 23.9 paragraph 2 (which refers to the report of the PCT assembly, 18th session (1991), item 24).

Notably, during the international stage of this application, the Examiner **did not** make a lack of unity finding and considered all of the claims to be directed to a single invention.

Plainly, the written restriction requirement fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under § 371. It is unclear how the Examiner could conclude that instant application now has five Groups of inventions, when the international application from which it originates has unity of invention.

Finally, according to the MPEP §803.01, there are two criteria for restriction between inventions which are alleged to be patentably distinct: 1) the inventions must be independent and distinct as claimed and 2) there must be a

serious burden on the Examiner if the restriction is not required.

Notably, claims 40 and 41 depend directly or indirectly from claim 1. Accordingly, it cannot be reasonably maintained that the invention encompassed by these claims is "independent as claimed". Thus, it is respectfully requested that these claims be rejoined with the Group I invention, namely claims 1-36 and 49-57.

In order to be fully responsive, Applicants hereby elect the claims of the Group I invention for prosecution at this time. Regarding the requirement for the election of species, Applicants elect the following:

Requirement A -leptin;

Requirement B -obesity;

Requirement C-ob/ob mice;

Requirement D -sand rats; and

Requirement E- iron-responsive element binding protein 2 (MOM34; page 97).

All of the claims of the Group I invention, with the exception of claim 7, read on the elected species.

Applicants reserve the right to file one or more continuing applications under 35 U.S.C. §120 on the subject matter of any claims finally held withdrawn from consideration in this application.

Favorable consideration leading to prompt allowance of the present application is respectfully requested.

Respectfully submitted,

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